

REMARKS

Claims 1-103 are pending in the application. Claim 103 is newly added. Support for the amendment to claim 103 can be found in original claim 1, and throughout the specification. Claims 2, 4, 5, 6, 21, 23-27, and 29 have been amended to reduce multiple claim dependencies or to depend from an elected claim.

RESTRICTION REQUIREMENT

In the Restriction Requirement, the Examiner requires Applicants to elect a single invention for prosecution on the merits from one of two patentably distinct inventions. The Examiner contends that this application contains the following inventions or groups of inventions which are not linked as to form a single general inventive concept under PCT Rule 13.1.

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| <b>Group I</b>    | Claim(s) 1 and 3-29, drawn to a composition comprising erythropoietin (Ep) and an EPIP.              |
| <b>Group II</b>   | Claim(s) 2 and 6-29, drawn to an EPEP (erythropoietin production producing peptide).                 |
| <b>Group III</b>  | Claim(s) 30-39, drawn to cells treated with an EPEP.   |
| <b>Group IV</b>   | Claim(s) 40, drawn to a method of administering Ep to a subject.                                     |
| <b>Group V</b>    | Claim(s) 41, drawn to a method of administering an EPIP and Ep to a subject.                         |
| <b>Group VI</b>   | Claim(s) 42-67 and 71, drawn to a method of administering an EPIP to a subject.                      |
| <b>Group VII</b>  | Claim(s) 68-70, drawn to a method for testing the ability of a substance to stimulate Ep production. |
| <b>Group VIII</b> | Claim(s) 72, 73 and 98-101, drawn to a method for making Ep in vitro.                                |
| <b>Group IX</b>   | Claim(s) 74-84, drawn to a method for method for making Ep in vivo.                                  |
| <b>Group X</b>    | Claim(s) 85, drawn to Ep.  |
| <b>Group XI</b>   | Claim(s) 86-91, drawn to a method of identifying signal molecules.                                   |
| <b>Group XII</b>  | Claim(s) 92-97, drawn to a method of cell therapy.   |

**Group XIII** Claim(s) 98-101, drawn to a method of making a cell that makes Ep.

**Group XIV** Claim(s) 102, drawn to a cell that makes Ep.

Applicants hereby provisionally elect Group II, as set forth in claims 2-29 and 103, with traverse. It is noted that claims 3-5 have been amended to depend from claim 2 or newly added claim 103, which also depends from claim 2. Regarding the election of species, applicants provisionally elect a) R<sup>1</sup>, R<sup>2</sup>, and R<sup>4</sup> are hydrogen, X is oxygen, L is polyalkylene, and R<sup>3</sup> is an hydroxy. Applicants respectfully request that the restriction requirement and species election be reconsidered and withdrawn for the following reason:

- **The Restriction Requirement does not comply with M.P.E.P § 803**

Without conceding that the claims in the various Groups are not patentably distinct, Applicants respectfully assert that the Action has not shown that a serious burden would be required to examine all of the pending claims of Groups I-XIV in the this application. Specifically, M.P.E.P § 803 provides:

If the search and examination of an application can be made without serious burden, the Examiner *must* examine it on the merits, even though it includes claims to distinct or independent inventions.  
(*Emphasis supplied.*)

Thus, for a restriction to be proper, the Office Action must satisfy the following two criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden. *See* M.P.E.P § 803.

The Office Action has not shown that the second requirement has been met. Specifically, the Office Action has not shown that it would be a serious burden to search and examine all of the groups together. Indeed, the Office Action has not even alleged that it would be a serious burden to search and examine all of the groups together. Consequently, reconsideration and modification or withdrawal of the restriction is requested.

Applicants also respectfully request that the requirement for species election be reconsidered, as the Examiner has not shown that a serious burden would result if all the species are examined together. M.P.E.P. § 803 provides that “[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the

merits, *even though it includes claims to distinct or independent inventions.*" (Emphasis added.)

Thus, for a restriction requirement to be proper, the Examiner must satisfy the following two criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121) and (2) the search and examination of the entire application cannot be made without serious burden. See M.P.E.P. § 803. Applicants note that the restriction requirement does not provide sufficient basis to indicate that examination of more than one of the "species" would overly burden the Examiner. Applicants thus respectfully request reconsideration of the election requirement. Applicants remind the Examiner that if the elected genus is found to be allowable, all of the species should also be found allowable.

**CONCLUSION**

Applicant awaits an action on the merits. Should the Examiner have any questions regarding this response, the Examiner is encouraged to contact the undersigned at the telephone number and address listed below.

A credit card payment submitted *via* EFS Web in the amount of \$555.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(3) is enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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Name of Person Mailing (Print/Type)	Janell T. Cleveland		
Signature	/ Janell T. Cleveland /	Date	July 10, 2009